

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Schuler et al.	Group Art Unit: 3772
Application No: 10/734,076	Examiner: Patel, Nihir B
Confirmation No: 7962	Attorney Docket No: NK.0130.00
Filed: December 10, 2003	
Title: METERED DOSE INHALER WITH LOCKOUT	November 5, 2008 San Francisco, California 94107

**SUPPLEMENTAL APPEAL BRIEF**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Final Rejection of January 24, 2008, the Notice of Appeal filed on May 20, 2008, and the Notice of Non-compliant Appeal Brief mailed on September 9, 2008, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences and provides this Supplemental Appeal Brief. Appellant continues to request the reversal of the Final Rejection.

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By: 

Melanie Hitchcock

Date: November 5, 2008

**(1) *Real Party in Interest***

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 201 Industrial Road, San Carlos, California 94707.

**(2) *Related Appeals and Interferences***

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

**(3) *Status of Claims***

Claims 1-30 are presently pending in the case. Claims 1-30 have been finally rejected. The rejection of each of claims 1-30 is hereby appealed.

**(4) *Status of Amendments***

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

**(5) *Summary of the Claimed Subject Matter***

As recited in claim 1, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (115) being moveable into the container (105) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The

device also comprises a contact member (145) in the housing (115), the contact member (145) being moveable between a first position (Figures 1A and 1B) and a second position (Figures 2A and 2B), wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the first position and is unable to contact the contact member (145) when in the second position (see page 8 lines 13-26).

As recited in claim 5, shown in Figures 6A and 6B, and discussed on page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (110) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The device also comprises a contact member (145) in the housing, the contact member (145) having a first configuration (Figure 6A) and a second configuration (Figure 6B), wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the first configuration in a manner which allows the metering valve (125) to be moved to the actuated position, and wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the second configuration in a manner which does not allow the metering valve (125) to be moved to the actuated position (see page 14 line 18 through page 15 line 6).

As recited in claim 10, shown in Figures 6A and 6B, and discussed on page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The device also comprises a contact member (145) in the housing (115), the contact member (145) being moveable from a first condition (Figure 6A) to a second condition (Figure 6B), wherein

when the contact member (145) is in the first condition, the metering valve (125) may contact the contact member (145) so as to allow the metering valve (125) to be moved to the actuated position, and wherein a portion of the metering valve (125) is able to contact the contact member (145) when in the second condition in a manner which does not allow the metering valve (125) to be moved to the actuated position (see page 14 line 18 through page 15 line 6).

As recited in claim 18, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The device also comprises a contact member (145) in the housing (115), wherein the metering valve (125) may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member (Figures 1A and 1B) and may not be actuated when the metering valve and/or the container is unable to contact the contact member (Figures 2A and 2B).

As recited in claim 20, shown in the embodiment of Figures 1A, 1B, 2A and 2B and the embodiment of Figures 6A and 6B, and discussed on page 7 line 18 through page 8 line 26 and page 13 line 27 through page 15 line 21, an aerosolization device comprises: a housing (115); a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant; and a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (110) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The device also comprises a contact member (145) in the housing, wherein the metering valve (125) may be moved to the actuated position when the metering valve (125) and/or the container (105) is able to contact the contact member

(145) in a rigid configuration (Figures 1A and 1B or Figure 6A) and may not be actuated when the metering valve (125) and/or the container (105) is unable to contact the contact member (145) in a rigid configuration (Figures 2A and 2B or Figure 6B).

As recited in claim 22, shown in Figures 1A, 1B, 2A and 2B, and discussed on page 7 line 18 through page 8 line 26, a method is provided for controlling the operation of an aerosolization device, the aerosolization device comprising a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position. The method comprises: positioning a contact member (145) in a first position (Figures 1A and 1B) where the contact member (145) may contact the metering valve (125) and/or the container (105) to allow the metering valve (125) to be moved to the actuated position; and positioning the contact member (145) in a second position (Figures 2A and 2B) where the metering valve (125) may not be moved to the actuated position.

As recited in claim 26, shown in Figures 1A, 1B, 2A and 2B and Figures 6A and 6B, and discussed on page 7 line 18 through page 8 line 26 and page 13 line 27 through page 15 line 21, a method is provided for controlling the operation of an aerosolization device, the aerosolization device comprising a container (105) comprising a reservoir (110) storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve (125) in communication with the reservoir (110), the metering valve (125) being moveable into the container (105) to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve (125) is moved to the actuated position. The method comprises configuring a contact member (145) in a first configuration (Figure 6A) wherein the contact member (145) may contact the metering valve (125) to allow the metering valve (125) to be moved to the actuated position and configuring the

contact member (145) in a second configuration (Figure 6B) wherein the metering valve (125) may contact the contact member (145) but may not be moved to the actuated position.

**(6) *Grounds of Rejection to be Reviewed on Appeal***

Appellant requests review of the Examiner's following grounds of rejection:

Claims 1-21 have been rejected under 35 U.S.C. §102(b) as being anticipated by Published PCT Application WO 92/07599 to Smith et al. (hereinafter Smith et al.).

Claims 22-30 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Smith et al. [Note that only claims 22-25 are explicitly rejected in the Final Office Action. Appellant presumes this to have been a clerical oversight and that the Examiner intended to reject claims 22-30.]

**(7) *Argument***

Appellant believes each of claims 1-30 are improperly rejected and are therefore allowable for the following reasons.

**The rejection of independent claim 1 and dependent claims 2-4 is improper**

The Examiner's rejection of claims 1-4 under 35 USC §102(b) as being anticipated by Smith et al is improper, and Appellant requests reversal thereof.

Smith et al. does not anticipate independent claim 1, for example. For a rejection under 35 USC §102 to be proper, the reference relied upon must disclose each and every element of the claimed invention. Non-disclosure of a single element, feature or limitation of the claim negates anticipation. Claim 1 is to an aerosolization device

comprising, inter alia, a metering valve that is moveable into a container to an actuated position so that a predetermined amount of the pharmaceutical formulation may be released and a contact member that is moveable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when in the first position and is unable to contact the contact member when in the second position. These positively recited features are not disclosed by Smith et al.

Smith et al. does not disclose a contact member moveable between a first and second position wherein the metering valve is able to contact the contact member in the first position and unable to contact the member in the second position. Operation of the Smith et al. device is described on pages 18 and 19 and shown in Figure 1 of the Smith et al. publication. To prevent actuation, movement of the canister (4) is prevented by blocking member (18). To allow actuation, the blocking member is moved aside which allows movement of the canister. When the canister is moved downwardly, the valve (6) contacts the housing so that it is compressed into the canister which causes actuation. As can be seen, there is no "contact member" as claimed by Appellant that the metering valve is able to contact and that is moveable between a first and second position. Since Smith et al. does not disclose this positively recited feature, it does not anticipate claim 1.

The Examiner's contentions made in the Final Office Action of January 24, 2008, are not sufficient to support a rejection under 35 U.S.C. §102(b). The Examiner posits on page 2 of the Final Office Action that element 18 of Smith et al. satisfies the contact member limitation of claim 1. This is not correct. Element 18 of Smith et al., as shown in Figure 1 and discussed on page 19 of Smith et al., is a "blocking member" that prevents downward movement of a canister (4) thereby preventing actuation of a valve (6). At no time is the valve able to contact the blocking member of Smith et al. Since claim 1 recites that the valve is "able to contact the contact member when in the first position" and since the blocking member (18) of Smith et al. does not meet this limitation, Smith et al. does not anticipate claim 1. The Examiner then goes on to

contend that the valve of Smith et al. need not be able to contact the blocking member of Smith et al. in order for the blocking member to satisfy the claimed language because the claimed language is allegedly only functional. However, the Examiner has improperly interpreted the claim language. The language in Appellant's claim 1 describes the structural interaction of the claimed structural element. In particular the "is able to" and "is unable to" language is used to describe the different positions of the contact member. The language is not directed merely to the manner in which the device is intended to be used. Accordingly, the language should be afforded patentable weight.

Appellant requests reversal of the rejection of claim 1 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 2-4 which depend from claim 1 and are not anticipated by Smith et al. for at least the same reasons as claim 1.

The rejection of independent claim 5 and dependent claims 6-9 is improper

The Examiner's rejection of claims 5-9 under 35 USC §102(b) as being anticipated by Smith et al. is improper, and Appellant requests reversal thereof.

Independent claim 5 is not anticipated by Smith et al. Claim 5 is to an aerosolization device comprising, inter alia, a metering valve and a contact member, the contact member having a first configuration and a second configuration, wherein a portion of the metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position and wherein a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position. Smith et al. does not disclose a device as set forth in claim 5. Smith et al. does not disclose a contact member having first and second configurations and specifically does not disclose a second configuration wherein the metering valve is able to contact the contact member in a manner which



does not allow the metering valve to be moved to the actuated position. Accordingly, Smith et al. does not anticipate claim 5.

Appellant requests reversal of the rejection of claim 5 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claims 6-9 which depend from claim 5 and are not anticipated by Smith et al. for at least the same reasons as claim 5.

The rejection of independent claim 10 and dependent claims 11-17 and 19 is improper

The Examiner's rejection of claims 10-17 and 19 under 35 USC §102(b) as being anticipated by Smith et al. is improper, and Appellant requests reversal thereof.

Smith et al. does not anticipate independent claim 10. Claim 10 is to an aerosolization device comprising, inter alia, a metering valve and a contact member, the contact member having a first condition and a second condition, wherein a portion of the metering valve is able to contact the contact member when in the first condition in a manner which allows the metering valve to be moved to the actuated position and wherein a portion of the metering valve is able to contact the contact member when in the second condition in a manner which does not allow the metering valve to be moved to the actuated position. Smith et al. does not disclose a device as set forth in claim 10. Smith et al. does not disclose a contact member having first and second conditions wherein in the second condition, the metering valve is able to contact the contact member in a manner which does not allow the metering valve to be moved to the actuated position. Accordingly, Smith et al. does not anticipate claim 10.

Appellant requests reversal of the rejection of claim 10 under 35 U.S.C. §102(b). In addition, Applicant requests reversal of the rejection of claims 11-17 and 19 which depend from claim 10 and are not anticipated by Smith et al. for at least the same reasons as claim 10.

The rejection of independent claim 18 is improper

The Examiner's rejection of claim 18 under 35 USC §102(b) as being anticipated by Smith et al. is improper, and Appellant requests reversal thereof.

Independent claim 18 is not anticipated by Smith et al. Claim 18 is to an aerosolization device comprising, inter alia, a metering valve, a container, and a contact member, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member and may not be actuated when the metering valve and/or the container is unable to contact the contact member. Smith et al. does not disclose that which is claimed in claim 18. In fact, Smith et al. operates in an opposite manner to that which is claimed. In Smith et al., the metering valve **may not be** actuated when the canister (4) contacts the blocking member (18) and **may be** actuated when the canister is unable to contact the blocking member. Therefore, Smith et al. discloses a system different from that which is claimed in claim 18 and does not anticipate the claim.

Appellant requests reversal of the rejection of claim 18 under 35 U.S.C. §102(b).

The rejection of independent claim 20 and dependent claim 21 is improper

The Examiner's rejection of claims 20 and 21 under 35 USC §102(b) as being anticipated by Smith et al. is improper, and Appellant requests reversal thereof.

Smith et al. does not anticipate independent claim 20 either. Claim 20 is to an aerosolization device comprising, inter alia, a container, a metering valve, and a contact member, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member in a rigid configuration and may not be actuated when the metering valve and/or the container is unable to contact the contact member in a rigid configuration. Smith et al. does not disclose a device that may not be actuated when a metering valve and/or container is

unable to contact a contact member in a rigid configuration. Accordingly, Smith et al. does not anticipate claim 20.

Appellant requests reversal of the rejection of claim 20 under 35 U.S.C. §102(b). In addition, Appellant requests reversal of the rejection of claim 21 which depends from claim 20 and is not anticipated by Smith et al. for at least the same reasons as claim 20.

The rejection of claims 22-30 under 35 U.S.C. 103(a) is improper

The Examiner's rejection of claim 22-30 under 35 USC §103(a) as being unpatentable over Smith et al. is improper, and Appellant requests reversal thereof.

Smith et al. does not render independent claim 22 unpatentable. Claim 22 is to a method of controlling the operation of an aerosolization device comprising, inter alia, positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuated position and positioning the contact member in a second position where the metering valve may not be moved to the actuated position. Smith et al. does not disclose, teach or suggest the claimed method. Smith et al., in contrast, teaches the use of a blocking member (18) that is positioned to contact the canister (4) to prevent actuation of the device. Thus, Smith et al. teaches the opposite of that which is claimed, namely that the contact member is positioned in a first position to allow the metering valve and/or container to contact the contact member to allow actuation. Since Smith et al. does not disclose or teach all that is claimed and since the Examiner has not provided any explanation as to how it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith et al. in a manner that would result in the claimed method, there is no prima facie case established and claim 22 is not rendered unpatentable under 35 U.S.C. §103(a).

Appellant requests reversal of the rejection of claim 22 under 35 U.S.C. §103(a). In addition, Appellant requests reversal of claims 23-25 which depend from claim 22

and are not rendered unpatentable by Smith et al. for at least the same reasons as claim 22. Furthermore, claim 23 recites that that second position is one where the contact member may not be contacted by the metering valve or the container. This second position is not disclosed, taught or suggested by Smith et al.

Smith et al. also fails to render independent claim 26 unpatentable under 35 U.S.C. §103(a). Claim 26 is to a method of controlling the operation of an aerosolization device comprising, inter alia, configuring a contact member in a first configuration wherein the contact member may contact a metering valve to allow the metering valve to be moved to an actuated position and configuring the contact member in a second configuration wherein the metering valve may contact the contact member but may not be moved to the actuated position. Smith et al. does not disclose, teach or suggest the claimed method. Smith et al. does not disclose a second configuration wherein a metering valve may contact a contact member but may not be moved to an actuated position. Since Smith et al. does not disclose or teach all that is claimed and since the Examiner has not provided any explanation as to how it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Smith et al. in a manner that would result in the claimed method, there is no prima facie case established, and claim 26 is not rendered unpatentable under 35 U.S.C. §103(a).

Appellant requests reversal of the rejection of claim 26 under 35 U.S.C. §103(a). In addition, Appellant requests reversal of the rejection of claims 27-30 which depend from claim 26 and are not rendered unpatentable by Smith et al. for at least the same reasons as claim 26.

## Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: 05 NOV 2009

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## **(8) Claims Appendix**

1. An aerosolization device comprising:
  - a housing;
  - a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;
  - a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and
  - a contact member in the housing, the contact member being moveable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when in the first position and is unable to contact the contact member when in the second position.
2. An aerosolization device according to claim 1 wherein the metering valve may be moved to the actuated position only when the contact member is in the first position.
3. An aerosolization device according to claim 1 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first position, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is unable to contact the contact member and cannot be moved into the container to the actuated position.
4. An aerosolization device according to claim 1 further comprising a controller adapted to selectively control the movement of the contact member.

5. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing, the contact member having a first configuration and a second configuration, wherein a portion of the metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position, and wherein a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position.
6. An aerosolization device according to claim 5 wherein the metering valve may be moved to the actuated position only when the contact member is in the first configuration.
7. An aerosolization device according to claim 5 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first configuration, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is able to contact the contact member but cannot be moved into the container to the actuated position.
8. An aerosolization device according to claim 5 wherein the contact member is rigid in the first configuration and is flexible in the second configuration.

9. An aerosolization device according to claim 5 further comprising a controller adapted to selectively control the configuration of the contact member.

10. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing, the contact member being moveable from a first condition to a second condition, wherein when the contact member is in the first condition, the metering valve may contact the contact member so as to allow the metering valve to be moved to the actuated position, and wherein a portion of the metering valve is able to contact the contact member when in the second condition in a manner which does not allow the metering valve to be moved to the actuated position.

11. An aerosolization device according to claim 10 wherein the first condition is a first position and wherein the second condition is a second position.

12. An aerosolization device according to claim 11 wherein first position is a position in the housing where the contact member may contact a portion of the metering valve.

13. An aerosolization device according to claim 10 wherein the first condition is a first configuration and wherein the second condition is a second configuration, and wherein the first configuration is a rigid configuration.

14. An aerosolization device according to claim 13 wherein the second configuration is a relatively flexible configuration.



15. An aerosolization device according to claim 10 wherein the metering valve may be moved to the actuated position only when the contact member is in the first condition.

16. An aerosolization device according to claim 10 wherein the container and the metering valve are moveable within the housing and wherein when the contact member is in the first condition, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second condition, the metering valve cannot be moved into the container to the actuated position.

17. An aerosolization device according to claim 10 further comprising a controller adapted to selectively control the condition of the contact member.

18. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing,  
wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member and may not be actuated when the metering valve and/or the container is unable to contact the contact member.

19. An aerosolization device according to claim 17 further comprising a controller adapted to selectively control when the metering valve may and may not be moved to the actuated position.

20. An aerosolization device comprising:  
a housing;  
a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant;  
a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and  
a contact member in the housing,  
wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member in a rigid configuration and may not be actuated when the metering valve and/or the container is unable to contact the contact member in a rigid configuration.

21. An aerosolization device according to claim 20 further comprising a controller adapted to selectively control when the metering valve may and may not be moved to the actuated position.

22. A method of controlling the operation of an aerosolization device, the aerosolization device comprising a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method comprising:

positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuated position; and

positioning the contact member in a second position where the metering valve may not be moved to the actuated position.

23. A method according to claim 22 wherein the second position is a position where the contact member may not be contacted by the metering valve or the container.

24. A method according to claim 22 comprising returning the contact member to the first position after a condition is met.

25. A method according to claim 24 wherein the condition is the passage of a predetermined amount of time.

26. A method of controlling the operation of an aerosolization device, the aerosolization device comprising a container comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve being moveable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method comprising:

configuring a contact member in a first configuration wherein the contact member may contact the metering valve to allow the metering valve to be moved to the actuated position; and

configuring the contact member in a second configuration wherein the metering valve may contact the contact member but may not be moved to the actuated position.

27. A method according to claim 26 wherein the first configuration is a rigid configuration.

28. A method according to claim 26 wherein the second configuration is a flexible configuration.

29. A method according to claim 26 comprising returning the contact member to the first configuration after a condition is met.

30. A method according to claim 29 wherein the condition is the passage of a predetermined amount of time.

**(9) Evidence Appendix**

none

**(10) Related Proceedings Appendix**

none